

Subject: Re: Story on research violations by UCSD ophthalmologist
From: Jill Castellano <jillcastellano@inewssource.org>
Date: 4/4/19, 1:57 PM
To: "Gianelli, Diane M (OASH)" <Diane.Gianelli@hhs.gov>, Brad Racino
<bradracino@inewssource.org>

Thanks, I appreciate you tracking that down.

Jill

On Thu, Apr 4, 2019 at 1:31 PM Gianelli, Diane M (OASH) <Diane.Gianelli@hhs.gov> wrote:

Hi Jill,

Here's what I found out.

- Although OHRP does receive FDA audit reports, there is no rule that requires FDA to send them to us, so it is highly likely that OHRP does not receive copies of all FDA audit reports on inspections where there may be overlap in jurisdiction. FDA's regulations on IRB review and oversight closely match DHHS regulations for Protection of Human Subjects, so we generally do not re-investigate issues that FDA has investigated or plans to investigate.

- Our database contains no record of the FDA audit report referenced by you in your April 2 email on the topic.

Hope it helps. If you use any of it, feel free to attribute to an HHS spokesperson.

Diane

From: Jill Castellano <jillcastellano@inewssource.org>
Sent: Tuesday, April 2, 2019 3:58 PM
To: Gianelli, Diane M (OASH) <Diane.Gianelli@hhs.gov>
Cc: Brad Racino <bradracino@inewssource.org>
Subject: Re: Story on research violations by UCSD ophthalmologist

Thanks! Yes, we reached out to them. Because the studies were actually funded

through the NIH, they suggested we speak to people within the Department of Health and Human Services.

On Tue, Apr 2, 2019 at 12:56 PM Gianelli, Diane M (OASH) <Diane.Gianelli@hhs.gov> wrote:

Hi Jill.

Pretty unlikely OHRP keeps track of FDA warning letters, but I'll ask around and see what I can find out.

Have you reached out to FDA on this?

Diane

From: Jill Castellano <jillcastellano@inewssource.org>
Sent: Tuesday, April 2, 2019 3:04 PM
To: Gianelli, Diane M (OASH) <Diane.Gianelli@hhs.gov>
Cc: Brad Racino <bradracino@inewssource.org>
Subject: Story on research violations by UCSD ophthalmologist

Hi Diane,

I hope you're doing well. This is Jill Castellano, reporter from inewssource in San Diego.

I'm reaching out because of a story Brad Racino (cc'd here) and I are working on about an ophthalmologist at the University of California San Diego named Dr. Kang Zhang. We came across an [FDA warning letter](#) and an audit (attached) that the UC system did of his research. Taken together, they found a number of violations across many of his research studies, including poorly managed staff, a lack of proper training, shoddy record keeping, improper billing of research subjects and patients enrolled who don't fit the enrollment criteria.

Because most of Dr. Zhang's research has been funded through the NIH, we are wondering if your office has been notified of these violations and if your office is looking into them. We'd also like to know in general if your office has some system to keep track of FDA warning letters and/or research audits — if your office is automatically notified when these are conducted or if your office keeps track of them on its own somehow.

I'm hoping to hear back from you by the end of the day Thursday if not sooner.

We appreciate the help. Thank you,

Jill Castellano

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Jill Castellano

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